JS 44 (Rev. 12/12)

CIVIL COVER SHEET

Under Seal

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

16-cv-289 16 0289

I. (a) PLAINTIFFS

Under Seal

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

James A. Kozachek, Esq.,
Cartusciello & Kozachek LLC
101 Farnsworth Avenue, Bordentown, NJ 08505 (609) 324-8200

DEFENDANTS

Under Seal

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☒ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
31 U.S.C. section 3729, et seq.

Brief description of cause:
False or fraudulent claims against government health care and health insurance programs

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER S.T.

DATE
January 22, 2016

SIGNATURE OF ATTORNEY OF RECORD
(James A. Kozachek) JAN 22 2016

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

Under Seal

GAM

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

16 0289

Address of Plaintiff: Counsel for Relators Jane Does: James A. Kozachek; Cartusciello & Kozachek, LLC; 101 Farnsworth Avenue, Bordentown, NJ 08505

Address of Defendant: 2181 East Aurora Road; Twinsburg, OH 44087

Place of Accident, Incident or Transaction: Nationwide

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☒ No☐ not apply

Does this case involve multidistrict litigation possibilities? Yes☐ No☒

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☐ No☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases (Please specify) False Claims Act

B. *Diversity Jurisdiction Cases:*

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases (Please specify) _____

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, James A. Kozachek, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 1-22-2016 Attorney-at-Law 62296 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 1-22-2016 Attorney-at-Law 62296 Attorney I.D.# JAN 22 2016

CIV. 609 (5/2012)

Under Seal

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GAM

CASE MANAGEMENT TRACK DESIGNATION FORM

Under Seal : CIVIL ACTION

v. :

Under Seal : NO. 16 0289

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

1/22/2016	James Kivlichan	Plaintiff - Relator
Date	**Attorney-at-law**	**Attorney for**
609 324 8200	609 324 8201	[redacted]jkivlichan@cklawllc.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JAN 22 2016

$400

GAM

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

[UNDER SEAL], Plaintiff[s], v. [UNDER SEAL], Defendant[s].	Civil Action No. 16 0289 **COMPLAINT AND JURY DEMAND** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

COMPLAINT

SEALED CASE – DO NOT PUT ON PACER

TABLE OF CONTENTS

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. JANE DOE 1 and JANE DOE 2, Plaintiffs, v. ENVISION TOPCO HOLDINGS, LLC AND ENVISION PHARMACEUTICAL HOLDINGS LLC D/B/A ENVISION AND/OR ENVISIONRX; ENVISION INSURANCE COMPANY; ENVISIONRX OPTIONS LLC; RITE AID CORPORATION; AND TPG GLOBAL, LLC, Defendants.	Civil Action No. **COMPLAINT AND JURY DEMAND** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

Through their undersigned attorneys, *qui tam* plaintiffs Jane Doe 1 and Jane Doe 2 ("Relators" or "Plaintiffs-Relators"), on behalf of the United States of America for this Complaint against Defendants, allege as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties, on behalf of the United States (the "United States" or the "Federal Government") arising from false and/or fraudulent statements, records, and claims made and caused to be made by the Defendants and/or their agents and employees against government health care and health insurance programs, failure to return overpayments, and conspiracy, all in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq*., as amended ("the FCA" or "the Act").

2. This health care fraud has been and continues to be committed by Defendants: Envision Topco Holdings, LLC and Envision Pharmaceutical Holdings LLC d/b/a Envision

and/or EnvisionRx; EnvisionRx Options LLC as a pharmacy benefit manager ("PBM");and Envision Insurance Company ("EIC" or "Envision Insurance"), as a Medicare Part D Plan Sponsor (collectively these companies constitute the "Envision Defendants," along with other companies and subsidiaries owned by or related to the Envision Defendants). Also liable are Defendant TPG Global, LLC, the owner of the Envision Defendants from about mid-2013 to June 2015, and the Defendant Rite Aid Corporation who has owned the Envision Defendants since June 2015. The fraudulent schemes alleged herein include:

a. EnvisionRx Options (as the PBM for EIC/Envision Insurance) submitted some 1.5 million false or fraudulent Prescription Drug Events ("PDEs" or claims) to the United States Department of Health and Human Services Centers for Medicare and Medicaid Services ("CMS") per month in 2015, and continues to do so in 2016. These PDEs are false or fraudulent because the "negotiated prices" listed for the drugs (and paid by CMS) are higher than the actual negotiated prices paid to the pharmacies by EnvisionRx Options as PBM. The actual negotiated price is lower because of "price concessions" made by the pharmacy to the Envision PBM that can reasonably be determined at the point-of-sale and as such must be reflected in the negotiated price on the claim/PDE submitted to and paid by CMS. However, EnvisionRx Options is concealing these price concessions, CMS is overpaying for the drugs, and the Envision Defendants are pocketing the overpayments. Moreover, on information and belief, Envision Insurance Company has concealed these fees in its Medicare Part D bid documents for plan years 2014 forward.

b. The "negotiated price" reported on the PDEs/claims in 2015 and 2016 is further false because it is based on an inflated Maximum Allowable Cost ("MAC") used by the

Envision PBM to pay the pharmacy for the claim so that the above-referenced price concessions being paid by the pharmacies are offset or "cost neutral" [to the pharmacy].

c. In addition, for plan years 2012-2014 (and continuing), the Envision Defendants have misrepresented to CMS the cost of Envision's E-prescribing services, have overcharged CMS for the same, and have not notified CMS of, or repaid, these overpayments, and have not adjusted or presented Medicare Part D bid proposals and related information truthfully.

d. Envision also engages in fraudulent activity causing double billing to Medicare Parts A, B and D, and other government health insurance programs, for prescription drugs, including, without limitation, for patients who use pharmacy Cash Cards and for patients in hospice, long term care, skilled nursing, and hospital facilities owned in whole or in part by Defendant TPG Global, LLC ("TPG"), a global private investment firm who owned the Envision Defendants from 2013-2015 and continues to have influence within Envision.

e. EnvisionRx Options has been processing pharmacy claims for prescriptions from providers who are sanctioned and/or unapproved, and is continuing to do so despite an audit. It has both intentionally removed all programming which would block claims from federal and/or state prescribers who have been sanctioned or otherwise do not have CMS approved prescribing authority, and intentionally failed to implement adequate point-of-sale programming, all despite knowledge of the issue.

3. Defendants' conduct alleged herein violates the federal False Claims Act. The federal False Claims Act (the "FCA") was originally enacted during the Civil War. Congress substantially amended the Act in 1986—and, again, in 2009 and 2010—to enhance the ability of the Government to recover losses sustained as a result of fraud against it. The Act was amended

after Congress found that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

4. The FCA prohibits, *inter alia*: (a) knowingly presenting (or causing to be presented) to the federal Government a false or fraudulent claim for payment or approval; (b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; (c) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government; and (d) conspiring to violate any of these three sections of the FCA. 31 U.S.C. §§ 3729(a)(1)(A)-(C), and (G). Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1).

5. For purposes of the FCA, a person "knows" a claim is false if that person: "(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that the defendants specifically intended to commit fraud. *Id.* Unless otherwise indicated, whenever the words

"know," "learn," "discover" or similar words indicating knowledge are used in this Complaint, they mean "knowingly" as defined in the FCA.

6. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal (without service on the defendants during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit. The person bringing the action is known under the FCA as the "relator."

7. Based on the foregoing federal FCA provisions, *qui tam* Plaintiffs-Relators seek, through this action, to recover damages and civil penalties arising from the Defendants' knowing fraud against the United States including its Medicare program. Defendants have defrauded the United States of tens of millions of dollars since at least 2012.

II. PARTIES

8. The real plaintiff party in interest to the FCA *qui tam* claims herein is the sovereign government of the United States of America. At this time, Plaintiffs-Relators are pursuing their cause of action on behalf of the named Plaintiff the United States on the FCA *Qui Tam* claims set forth herein pursuant to 31 U.S.C. § 3730(b).

9. Plaintiffs-Relators Jane Doe 1 and Jane Doe 2 are citizens of the United States. They are familiar with and have personal knowledge of the Defendants' business operations and the allegations herein. Further details regarding Relators and their knowledge have been and will continue to be provided to the United States.

10. Defendants Envision Topco Holdings, LLC and Envision Pharmaceutical Holdings, Inc. (collectively referred to herein as "Envision" or "EnvisionRx") are Delaware limited liability companies, headquartered in Twinsburg, Ohio. The Envision Group is

comprised of numerous related subsidiaries involved in health care services including Defendants EnvisionRx Options LLC and Envision Insurance Company. Envision was originally founded/owned by Barry Katz, Jim Mindala, and Kevin Nagle in approximately 2001. In the second half of 2013, Defendant Envision was acquired by Defendant TPG Global, LLC ("TPG"), a global private investment firm and other shareholders for some $800 million. In June 2015, TPG sold Envision to Defendant Rite Aid Corporation (NYSE:RAD) in a transaction valued at approximately $2 billion, with around $1.8 billion in cash and 27.9 million Rite Aid shares. Envision/EnvisionRx functions as a wholly owned subsidiary of Defendant Rite Aid Corporation.

11. Defendant Envision Insurance Company ("Envision Insurance" or "EIC"), is one subsidiary of Envision. Defendant EIC, headquartered in Twinsburg, Ohio, has operated as a Medicare Part D Product Plan Sponsor ("PPS") since 2007, when it was approved by CMS to be a PPS, i.e., to offer and administer a Medicare Part D Prescription Drug Plan ("PDP"). Each year since, EIC has bid on and been approved as a Medicare Part D PPS.

12. Defendant Envision Insurance/EIC operates in all fifty states. According to published CMS reports, in 2015 Envision Insurance Company had 385,593 Part D PDP members of which 338,398 (almost 90%) receive low income subsidies ("LIS"), one of several types of CMS Medicare Part D payments.

13. Defendant EnvisionRx Options, LLC ("EnvisionRx Options"), is a pharmacy benefits manager or PBM, also headquartered in Twinsburg, Ohio. Like Defendant Envision Insurance, Defendant EnvisionRx Options operates in all fifty states. EnvisionRx Options (also known as Envision Pharmaceutical Services, see www.envisionrx.com) serves as the PBM for Defendant Envision Insurance/EIC as well as other health insurance companies. According to

news reports around June 2015, "Established in 2001, EnvisionRx Options is a national, full-service pharmacy benefit management (PBM) company with consolidated revenues in excess of $4 billion. *The company provides both transparent and traditional PBM options through its EnvisionRx Options and MedTrak PBMs, respectively, as well as pharmacy-related services to clients across the nation.* EnvisionRx Options also offers fully integrated mail-order and specialty pharmacy services through Orchard Pharmaceutical Services; access to the nation's largest cash pay infertility discount drug program via Design Rx; an innovative claims adjudication software platform in Laker Software*; and a national Medicare Part D prescription drug plan through Envision Insurance Company's EnvisionRx Options Plus product offering. Information about EnvisionRx Options, which is a wholly owned subsidiary of Rite Aid Corporation, is available through the company's website ....*" In 2015, EnvisionRx Options had annual sales of $5 billion, up from less than $2 billion in 2011.

14. Defendant Rite Aid Corporation (NYSE:RAD) ("Rite Aid"), current owner of the Envision Defendants, is one of the nation's leading drugstore chains with nearly 4,600 stores in 31 states and the District of Columbia. A Fortune 500 company, it is headquartered in Camp Hill, Pennsylvania, and had fiscal 2015 annual revenues of $26.5 billion. As noted above, Defendant Rite Aid acquired Defendant Envision in June 2015 from Defendant TPG. In October 2015, it was announced that The Walgreen Company will acquire Rite Aid for $17.2 billion. The Rite Aid shareholder vote is scheduled for February 4, 2016, but required regulatory, etc. approvals and due diligence are likely to take 6-12 months. The Walgreen Company is the largest drug retailing chain in the United States. As of May 31, 2014, the company operated 8,217 stores in all 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands,

however, it lacks a PBM, something Rite Aid now has through its June 2015 acquisition of Envision.

15. Defendant TPG Global, LLC ("TPG"), is a global private investment firm. According to TPG, it is a leading global private investment firm founded in 1992 with over $74 billion of assets under management and offices in San Francisco, Fort Worth, Austin, Dallas, Houston, and New York, as well as internationally; TPG has extensive experience with global public and private investments executed through leveraged buyouts, recapitalizations, spinouts, growth investments, joint ventures and restructurings; and the firm has a well-known history of healthcare investing including Adare Pharmaceuticals, Aptalis, EnvisionRx Options, Fenwal, Healthscope, IASIS Healthcare, Immucor, IMS Health, Par Pharmaceutical, Quintiles Transnational and Surgical Care Affiliates, among others. *See* www.tpg.com.

III. JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

17. Although such issue is no longer jurisdictional under the 2010 amendments to the FCA, to Relators' knowledge, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e). Moreover, whether or not such a disclosure has occurred, Relators would qualify under that section of the FCA as an "original source" of the allegations in this Complaint. Before filing this action, Relators voluntarily disclosed and provided to the Government the information on which the allegations or transactions in this action are based. Additionally, Relators have knowledge about the misconduct alleged herein that is independent of, and that would materially

add to, any publicly disclosed allegations or transactions that may prove to have occurred without their knowledge.

18. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process, because Defendants are related corporate entities that have engaged in concerted misconduct as alleged herein, and because all Defendants have minimum contacts with the United States. Moreover, one or more Defendants can be found in and transacts substantial business in this district, including business related to Defendants' concerted misconduct.

19. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants have engaged in concerted misconduct as alleged herein, and because one or more Defendants can be found in and transacts business in this district, including business related to Defendants' concerted misconduct.

IV. RELEVANT FEDERAL LAWS

A. The Medicare Program

20. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program. Medicare is a federally-funded health insurance program primarily benefiting the elderly. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 *et seq*. The Medicare program is administered through the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

21. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A ("Part A"), the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. *See* 42 U.S.C. §§ 1395c-1395i-4.

Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. *See* 42 U.S.C. §§ 1395k, 1395l, 1395x(s). Medicare Part C covers certain managed care plans, and Medicare Part D, as described further below, provides subsidized prescription drug coverage for Medicare beneficiaries.

1. Overview of Medicare Part D

22. Medicare Part D took effect on January 1, 2006 pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"). This law extended prescription drug coverage to all Medicare eligible persons who choose to participate in Part D Prescription Drug Plans ("PDPs"). After receiving bids, nine or ten entities were chosen by CMS to offer PDPs pursuant to Part D; these entities are known as Part D Product Plan Sponsors ("PPS"). CMS approved the bids in mid-September 2005, and contracts between CMS and the PPSs were signed on or about September 15, 2005. Winning bidders began marketing their plans October 1, 2005.

23. Every year since, CMS has received bids and has awarded contracts to companies to act as PPSs and offer PDPs. Plans/PDPs are based on a calendar year and the bidding process begins several months before the plan/calendar year. For example, for plan year 2016 that began on January 1, 2016, bids were submitted in early spring 2015; awarded in summer 2015; went to contract in September 2015; began enrolling members on October 1, 2015; and were effective on January 1, 2016. During the bid and award process, the PPS is required to notify CMS within 30 days if anything material changes. Failure to notify CMS appropriately can affect the administrative reimbursement rate, it can affect the "benchmark" set by CMS for the amount it

agrees to pay to cover the monthly premium for an LIS plan member in a given state, and there could be sanctions placed on the plan such as barring it from auto-enrolled patients/members (the majority of Defendant Envision Insurance/EIC's members are auto-enroll).

24. Pursuant to the MMA and the PDP, CMS provides for and pays a portion of the premium for members (Medicare beneficiaries) and for expenses using *direct* and *indirect* subsidies and *prospective and retroactive* payments. The benefit allows Medicare payment to plans that contract with CMS to provide qualified Part D prescription drug coverage. The law provides four payment mechanisms and, *as a condition of payment, requires* that plans submit data and information necessary for CMS to carry out those payment provisions. These four "payment mechanisms" are: direct subsidy; LIS (i.e. low income subsidy); reinsurance subsidy; and risk sharing. Factors *and* actual costs must be reported. CMS makes *prospective* payments to PPSs that cover three of the subsidies (direct, LIS, and reinsurance). Then, after the end of the Plan year, there is a final reconciliation of the direct subsidy and the "risk sharing" based in part on risk adjustment factors *and* actual costs reported. After final reconciliation, *retroactive* payments are made to the PPS as warranted.

25. Under this model, CMS makes *prospective* payments to a Part D PPS such as Defendant Envision Insurance/EIC. PBMs such as Defendant EnvisionRx Options, acting on behalf of the Part D PPSs such as Defendant EIC, contract with dispensing pharmacies to cover the Medicare beneficiaries/patients in the PPS' plan/ network. These pharmacies submit claims for payment for the PPS' Medicare members' prescriptions to a pharmacy benefit manager ("PBM") for the PPS; in the case of Defendant EIC, Defendant EnvisionRx Options is the PBM. The submission of the claim for payment for a prescription drug is referred to as a Prescription Drug Event ("PDE"). The PBM, such as Defendant EnvisionRx Options, is then responsible for

administering the claims: it submits the claims to CMS *on behalf of* the PBM's client PPS, it receives payment from CMS, and in turn pays the pharmacy within a prescribed period of time.

2. Reporting of "Negotiated Price" and Other Cost Data to CMS

26. As a condition of payment, PPSs, including Defendant EIC, must submit data and information necessary for CMS to reconcile costs and calculate prospective *and* retroactive payments. The PDE record is structured to report data to make these payments. For example, CMS uses the data to reconcile the low income cost-sharing subsidy and reinsurance payments and to implement risk sharing.

27. Among the key data are the "negotiated prices" being reported on the PDE. Negotiated prices are the payment amounts pharmacies receive pursuant to contracts with the PBM for covered Part D drugs dispensed to plan members. This data is submitted to CMS by the PBM via a bi-weekly PDE submission which should report the "negotiated prices" that the pharmacies *actually receive* from the PBM *and retain* on a Part D claim.

28. CMS payments to plans are based on the reporting of *negotiated prices* through PDE reporting (including any discounts, subsidies, rebates, or other price concessions calculable at the time of the PDE), *that are actually paid to the pharmacy*, and are later offset by any other price concessions submitted in aggregate through the separate annual Direct and Indirect Remuneration (DIR) reporting process. DIR includes discounts, cash discounts, chargebacks, rebates, up-front payments, and other price concessions that would serve to decrease the costs incurred by the Part D sponsor for the drug. 79 FR 29843, 29876 (May 23, 2014).

29. CMS has regulated the definition of "negotiated price" and how it is to be treated in Part D benefit administration and in payment reconciliation. Since 2010, the regulatory definition found at 42 C.F.R. § 423.100 has been:

> "*Negotiated prices means prices for covered Part D drugs that: (1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy, or other network dispensing provider, have negotiated as the amount such network entity will receive, in total, for a particular drug*; (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and DIR [direct or indirect subsidies] that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) Include any dispensing fees."

42 C.F.R. § 423.100 (emphasis added).

30. CMS has proposed amending the existing definition of "negotiated prices" to clarify that clause 2 of the existing definition refers primarily to price concessions from parties other than pharmacies, and "to allow a narrow exception to the requirement that all pharmacy price concessions be included in the negotiated price for those contingent pharmacy price concessions that cannot reasonably be determined at the point of sale [and thus would be reported on the annual DIR report]." 79 FR 29843, 29876 (May 23, 2014).

31. On September 29, 2014, CMS issued a Memorandum to provide proposed draft guidance for Part D PPSs on reporting DIR data for pharmacy price concessions for (CY) 2016 and beyond. In this Memorandum, CMS referenced its "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" in which it expressed concerns regarding the differences with which Part D PPSs report costs and price concessions to CMS. CMS noted that some Part D PPSs report certain pharmacy price concessions as DIR rather than as price concessions that affect the negotiated price, and stated that "we believe it is critical that negotiated prices reported on the PDE data have a consistent meaning across the Part D program in order to preserve a level playing field in bidding and cost reporting." *See* 79 FR 29843, 29878 (May 23, 2014) quoted in CMS Memorandum dated September 29, 2014 to "All Part D Sponsors and interested parties" regarding "Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions."

32. The CMS Memorandum's draft guidance further states that for the purposes of reporting, pharmacy price concessions can be broken down into two categories – those that can reasonably be determined at point-of-sale and those that cannot. Any pharmacy price concession or incentive payment that can reasonably be determined at point-of-sale *must* be included in the negotiated price and reported on the PDE. (emphasis added) The requirements for reporting price concessions apply regardless of how the price concessions are characterized by the Part D PPS, the PBM, the pharmacy, or any other entity and regardless of whether the price concession is calculated on a per claim basis. Price concessions that cannot reasonably be determined at point-of-sale are reported to CMS later, on a DIR report due approximately three months after the end of the plan year (i.e. for plan year 2015, ending December 31, 2015, the report is due by April 1, 2016). CMS further noted its view that most pharmacy price concessions can reasonably be determined at point of sale and, therefore, should be reported through the negotiated price.

3. E-Prescribing

33. E-prescribing occurs when a prescriber uses a computer or an electric hand-held device, such as a personal digital assistant, to write and send a prescription directly to a dispenser. Before a prescriber sends a prescription to a dispenser, he or she can request electronic data regarding patient eligibility, formulary and benefits, and medication history from the patient's health insurance plan.

34. Prescriber access to prescription information, such as medication history and formulary information, has several potential benefits. With access to medication history, prescribers can potentially avoid adverse drug events, such as drug-to-drug allergies or interactions. In addition, prescribers can use e-prescribing systems to look up and prescribe lower cost alternative drugs listed on a patient's formulary.

35. The MMA established the Medicare Part D e-prescribing program. MMA, P.L. No. 108-173 §101(a); Social Security Act, §1860D-4(e); 42 U.S.C. § 1395w-104(e). For this program, CMS requires plan sponsors to implement four e-prescribing standards to provide the technical infrastructure that supports interoperable e-prescribing systems. A standardized technical infrastructure enables plan sponsors, prescribers, and dispensers to exchange prescription information with each other.

36. While plan sponsors must implement CMS defined e-prescribing standards, prescribers and dispensers are not required to adopt or support e-prescribing. To encourage prescribers to adopt e-prescribing, some plan sponsors offer e-prescribing initiatives, which include a combination of technology and services. Plan sponsors can also promote e-prescribing by providing prescribers and dispensers with financial incentives. MMA, P.L. No. 108-173 § 102(b); Social Security Act, §1852(j)(7); 42 U.S.C. § 395w-22(j)(7).

37. Plan sponsors' financial incentives may include pay-to-participate, pay-for-performance, and pay-per-transaction incentives. Pay-to-participate incentives are one-time grants given to prescribers to assist with startup costs. Pay-for-performance incentives are bonuses paid to prescribers for meeting specified e-prescribing metrics or outcomes. Pay-per-transaction incentives are bonuses given to prescribers every time they e-prescribe.

38. The MMA required HHS-OIG to establish an e-prescribing safe harbor rule to the Medicare and Medicaid Fraud and Abuse Statute, 42 U.S.C. § 1320a-7b(b) ("the Anti-Kickback Statute" or "AKS"), which prohibits payment in return for patient referrals. MMA, P.L. No. 108-173 §101(a); Social Security Act, § 1860D-4(e)(6); 42 C.F.R. § 1001.952(x). The e-prescribing safe harbor rule can be found at 42 C.F.R. § 1001.952(x).

4. The Prescription Drug Benefit Manual

39. The Prescription Drug Benefit Manual published by CMS (Prescription Drug Manual) details a program to control fraud, waste and abuse for plan sponsors (such as EIC) and pharmacy benefit managers (such as EnvisionRx Options). Chapter 9 provides both interpretative rules and guidelines for Part D PPSs on how to implement the regulatory requirements under 42 C.F.R. § 423.504(b)(4)(vi)(H), to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste, and abuse as an element of their compliance plan. The chapter identifies examples of plan sponsor fraud. The relevant ones to the case at hand are:

> *Improper bid submissions*: The Sponsor inappropriately overestimates or underestimates the bid to manipulate risk corridors and/or payments, including miscalculations of administrative ratio costs within the bids (wrong service lines).
>
> *Multiple billing*: Several payers billed for the same prescription, except as required for coordination of benefit transactions, such as the same prescription being covered and paid for under Medicare Part A or Part B, and then a second time under Part D, and/or possibly Medicaid.
>
> *False information*: Plan misrepresents or falsifies information it furnishes to CMS or to an individual under the Part D drug benefit program.
>
> *Inaccurate data submission*: Sponsor submits inaccurate or incomplete prescription drug event (PDE) data or Part D plan quarterly data.
>
> *Failure to disclose or misrepresentation of rebates, discounts or price concessions*: Sponsor fails to disclose or misrepresents rebates, discounts, price concessions, or other value added gifts, including concessions offered by pharmaceutical manufacturers.

B. Federal False Claims Act

40. The federal False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(l), provides for the award of treble damages and civil penalties against a defendant for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States government. When submitting a claim for payment, a provider does so subject to and under the terms of his

certification to the United States that the services were delivered in accordance with federal law, including, for example, those governing the Medicare Program. Compliance with these certifications is a material condition of payment, and claims that violate these certifications are false or fraudulent claims under the False Claims Act. CMS and its fiscal agents will not pay claims for services or claims for services provided in violation of relevant federal laws.

41. The federal False Claims Act, 31 U.S.C. § 3729, as amended by the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 (("FERA'') enacted May 20, 2009, provides, in relevant part:

> (a) LIABILITY FOR CERTAIN ACTS.(1) IN GENERAL – Subject to paragraph (2), any person who –(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B)...or (G). . . or (G) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil penalty of not less than [$5,500] and not more than [$11,000] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1). The FCA further provides:

> (b) ACTIONS BY PRIVATE PERSONS. (1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government.

31 U.S.C. § 3730(b)(1).

42. The FCA defines a "claim" to include "any request or demand, whether under a contract or otherwise, for money or property" that "is made to a contractor, grantee, or other recipient" if the United States Government provides "any portion of the money or property" which is "requested or demanded," or if the Government "will reimburse such contractor,

grantee, or other recipient for any portion of the money or property which is requested." 31 U.S.C. § 3729(b)(2).

43. The FCA, 31 U.S.C. § 3729(b)(1), provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

44. The FCA, 31 U.S.C. § 3729(b)(4), provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

45. The FCA defines an "obligation" to pay as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-guarantee, or licensor licensee relationship, from a fee-based or similar relationship, from statute or regulation, *or from the retention of any overpayment*." 31 U.S.C. § 3729(b)(3) (emphasis added). Moreover, in the health care context, such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment…is an obligation (as defined [in the FCA])", and an overpayment must be reported "By the later of…60 days after the date on which the overpayment was identified…or the date any corresponding cost report is due, if applicable." Patient Protection and Affordable Care Act, March 23, 2010 ("PPACA"), Pub. L. 111-148 (Mar. 23, 2010), Section 6404(a), codified at 42 U.S.C. § 1128J9(d). *See also* 42 U.S.C. § 1320a-7k(d).

C. The Anti-Kickback Laws of the United States

46. The Medicare and Medicaid Fraud and Abuse Statute (the "Anti-Kickback Statute" or "AKS"), 42 U.S.C. § 1320a-7b(b), was enacted under the Social Security Act in 1972 and has been amended many times since. The Anti-Kickback Statute arose out of Congressional concern that payoffs to those who can influence health care decisions corrupts medical decision-making and can result in goods and services being provided that are medically inappropriate, unduly costly, medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of government health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

47. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute's prohibition applies to both sides of an impermissible kickback relationship (i.e., the giver and the recipient of the kickback). The statute provides, in pertinent part:

> (b) Illegal remunerations**
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> a. To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
>
> b. To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

48. Violations of the federal AKS can subject the perpetrator to liability under the federal FCA, for example, for causing the submission of false or fraudulent claims or for making a false or fraudulent statement or record material to a false or fraudulent claim. *See* PPACA, *supra*, amending the federal AKS, 42 U.S.C. §1320a-7b, to add new subsections (g) and (h) (items or services resulting from a violation of the AKS constitute false or fraudulent claims for purposes of the federal FCA and no actual knowledge of this section or specific intent to commit a violation of this section is required). Accordingly, claims for reimbursement for services that result from kickbacks are rendered false or fraudulent under the False Claims Act. 42 U.S.C. § 1320a-7b(g). The Anti-Kickback Statute contains safe harbors that exempt certain transactions from its prohibitions. *See* 42 U.S.C. § 1320a-7(b)(3).

49. Once the Government has demonstrated each element of a violation of the Anti-Kickback Statute, the burden shifts to the defendant to establish that defendant's conduct at issue was protected by such a safe harbor or exception. The Government need not prove as part of its affirmative case that defendant's conduct at issue does not fit within a safe harbor.

50. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. § 1320a-7(b)(7), 1320a-7a(a)(7).

51. Compliance with the Anti-Kickback Statute is a precondition to participation and to payment as a health care provider under Medicare. *See generally United States ex rel. Wilkins*

v. United Health Group, Inc., 659 F.3d 295 (3d Cir. 2011); United States ex rel. Hutcheson v. Blackstone Medical, Inc., 647 F.3d 377 (1st Cir. 2011).

52. Either pursuant to provider agreements, claim forms, or other appropriate manner, providers who participate in a federal health care program including Medicare Part D generally must certify that they have complied with all applicable federal rules and regulations, including the Anti-Kickback Statute.

53. Any party criminally convicted under the Anti-Kickback Statute must be excluded (i.e., not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a criminal conviction, if the Secretary of HHS finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agencies to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

54. The enactment of these various provisions and amendments demonstrates Congress' commitment to the fundamental principle that federally funded health care programs such as Medicare will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback Statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare, Medicaid and other federally funded health care programs.

V. FACTS AND ALLEGATIONS

A. Summary of Defendants' Unlawful Conduct

55. Defendants have engaged in ongoing fraudulent schemes to defraud government health care programs, most notably Medicare Part D. These schemes, which have cost the

government tens of millions of dollars since 2012, impact CMS' bid calculations and award of Medicare Part D PPS contracts, as well as its prospective and retrospective payments to Defendant EIC as a PPS, and its payment of pharmacy claims by Defendant EnvisionRx Options as a PBM for Defendant EIC. Among the ways in which Defendants have carried out this scheme are by: (a) reporting false or fraudulent negotiated prices in the PDEs to CMS; (b) inflating Maximum Allowable Cost ("MAC") including in PDEs submitted to CMS; (c) misrepresenting E-Prescribing costs and not reporting or refunding any of the related overpayments to CMS; (d) double billing for drugs under government health care programs, including Medicare Parts A, B and D; and (e) processing claims for sanctioned and/or unapproved prescribers.

56. Through these schemes, which are detailed further below, Defendants have defrauded the United States of tens of millions of dollars and the fraud is ongoing. In the process, the Defendants have unjustly enriched themselves. Defendant TPG acquired Envision from its original founders/owners (Barry Katz, Jim Mindala and Kevin Nagle) for some $800 million in the second half of 2013. http://www.themiddlemarket.com/news/tpg-buys-envision-pharmaceutical-242037-1.html. Then, in June 2015, less than two years after it acquired Envision, TPG sold Envision Pharmaceutical Holdings LLC/Envision Rx/Envision to Defendant Rite Aid Corp. (NYSE:RAD) in a transaction valued at approximately $2 billion, with around $1.8 billion in cash and 27.9 million Rite Aid shares. See more at: http://americanpharmacynews.com/stories/510550830-rite-aid-successfully-acquires-EnvisionRxOptions#sthash.sisWZQgT.dpuf. In other words, in less than two years, Envision increased *two and one-half times* in value. The fraudulent schemes are continuing under new ownership by Defendant Rite Aid, with the profitability of the Envision PBM reportedly being

one factor in Walgreen's interest in acquiring Rite Aid as noted above. And, while Defendant TPG sold its interest in Envision to Rite Aid as of June 2015, TPG still has influence in and common interests with Envision as people who Defendant TPG hired into Envision Defendants as CEO, President, and managers, are still with Envision.

B. "Negotiated Prices" Reported in the PDEs to CMS are False or Fraudulent Because "Preferred Pharmacy" and Other Fees Are Not Included

57. Defendant EnvisionRx Options acts as a PBM for multiple client PPSs, including Defendant EIC, and in that capacity, on behalf of its clients, including Defendant EIC, Defendant EnvisionRx Options contracts with pharmacies for access to the PBM's network. A pharmacy must be a member of the PBM's network in order to process and dispense prescription drugs for the PBM's/PPS's Medicare Part D plan members.

58. In the early part of 2014, Defendant EnvisionRx Options began charging a Network Administration and Technology Fee ("NATF"), an administrative fee ranging from $.04-$.12 per claim paid to the PBM by the pharmacy for costs associated with processing claims under Medicare Part D (previously Defendant EnvisionRx Options had charged such a fee only on private insurance for Part D—not on Medicare).

59. Then, in April 2014, Defendant EnvisionRx Options began planning for an additional fee, in the nature of a "preferred pharmacy fee" that would be charged on each Medicare Part D claim/prescription for an Envision Insurance/EIC member. Initially, this "deal" was being offered only to Walgreens, however, EnvisionRx Options then approached all the major pharmacies. These pharmacies at first balked at the idea, but then signed up by November 2014 or so for the calendar/plan year 2015. Consequently, by December 2014/January, 2015, Defendant EnvisionRx Options had offered preferred membership to all of its network

pharmacies and initiated a fee of approximately $5.00-$5.50 per Envision Insurance/EIC claim/prescription processed for pharmacies that chose to participate.

60. In meetings with the major pharmacy chains beginning in spring 2014, EnvisionRx Options described the proposed preferred pharmacy fee as "cost neutral," stating that it would be a "business driver" for those who participated. The implicit threat was that if a pharmacy declined to participate as a preferred pharmacy and pay the fee, it would not be part of EnvisionRx Options' network of pharmacies and could not process any claims for EIC patients and possibly lose that stream of revenue from other PPSs that are represented by EnvisionRx Options. While EnvisionRx Options administers claims for multiple PPSs, it "offered" a preferred network *only for EIC claims* and the fees for the preferred pharmacies were assessed *only on claims for EIC members*.

61. The preferred pharmacy fee (like the NATF) is a flat fee per EIC claim and calculable for purposes of determining the "negotiated price" for payment to the pharmacy, reporting to CMS, and calculating CMS reimbursement to the PPSs. However, EnvisionRx Options' electronic claims/PDEs sent to CMS do not reveal the preferred pharmacy fee or the NATF that is charged to the pharmacies pursuant to the contracts between the PBM and the pharmacies. Instead, a "logic" was designed by Defendant EnvisionRx Options, first to intentionally hide the NATF, and then to hide the preferred pharmacy fee, from CMS, while earmarking the claim for EnvisionRx Options later to ensure that the fees would be deducted prior to payment being sent to the pharmacy.

62. When Defendant EIC PDP members present their prescriptions to a preferred pharmacy, the pharmacy contacts the PBM EnvisionRx Options electronically to determine coverage and co-pay information. Defendant EnvisionRx Options responds electronically with

the requested information and the EnvisionRx Options' computer system makes note of the pharmacy code and EIC member ID, which identifies the pharmacy as a member of the preferred network and EIC as the PPS. The claim is flagged as such, and the preferred pharmacy fee and NATF information is *not included* in the claim. The claim is forwarded to CMS by EnvisionRx Options as the PBM (on behalf of Defendant EIC) without the fee information, and CMS submits payment to EnvisionRx Options and the PBM forwards payment to the pharmacy – *minus the preferred pharmacy fee and the NATF which Defendant Envision Rx takes out and retains prior to paying the pharmacy.*

63. Both this preferred pharmacy fee and the NATF can "reasonably be determined" at the point of sale, but are not disclosed as part of the "negotiated price" on the PDE. Thus, all the PDEs by Defendant EnvisionRx Options for EIC PDP plan members involving preferred pharmacies (i.e. claims to Medicare for these prescription drugs) since January 2015, are false or fraudulent and actionable under the FCA. Defendant EnvisionRx Options is liable under the FCA as it files the claims with CMS on behalf of EIC, and Defendant EIC is also liable under a "causing to be submitted" or as part of a conspiracy, and also has submitted incomplete and false bid information to CMS. Defendant EnvisionRx Options acted knowingly, as the PBM intentionally created a "logic" in their electronic claims program to hide the preferred pharmacy fee and NATF from CMS. Furthermore, Defendant EIC has been a PPS/plan sponsor for some eight years, and is presumed to be familiar with the Medicare Part D laws and regulations and the Prescription Drug Manual which identifies this conduct as fraud (false information; inaccurate data submission).

64. The pharmacies' membership in the preferred network provides no benefit to the PDP or ultimately CMS yet more than 90% of Defendant EnvisionRx Options' network

pharmacies are preferred. The per claim fees cost Medicare significantly more money, thus knowledge of the fees would be material to CMS' reimbursement and payments and bid calculations. For example, during Defendant Rite Aid Corp.'s due diligence process when it was acquiring Envision, Rite Aid asked Envision for a report showing the preferred pharmacy fees it had paid; the report Envision provided to Rite Aid Corp. showed that it had "paid" $383,000 in preferred pharmacy fees to EnvisionRx Options for just one month of claims. As Rite Aid is one of seven major pharmacies in this preferred pharmacy program, Relators estimate that the total monthly preferred pharmacy fees total approximately $2.6 million/month. Thus, for 2015, the total fees are approximately $31.2 million. The NATF adds to the total damages. The preferred pharmacy fee and the NATF affected approximately 1.5 million claims/month in 2015, for a total of some 18 million claims that year.

65. All Defendants have "knowledge" of this fraudulent scheme within the meaning of the FCA. Moreover, the scheme is continuing in 2016, albeit with a somewhat different veneer. For calendar/plan year 2016, EnvisionRx Options has *increased* the preferred pharmacy fee from approximately $5.00-$5.50 to approximately $8.50 but added a supposed opportunity for the pharmacy to earn a credit based on the pharmacy's Generic Dispensing Rate ("GDR") for the year. Thus, at the end of the year, if the pharmacy has met its GDR (i.e. a particular % of their scripts were generic, as set forth in the contract), then a reconciliation takes place to determine the reduced pharmacy fee for that year. In theory, the pharmacy would then receive a rebate. With this plan, it would appear that EnvisionRx Options is encouraging the pharmacies to fill prescriptions with generics. In theory, generics are good for the plan (and for Medicare), as they are cheaper. However, that financial benefit is lost, as Envision is inflating the MACs on these generic scripts. Moreover, on information and belief, the GDR formula is, in fact, an

unrealistic goal for the pharmacies, one that EnvisionRx Options does not expect any pharmacy will be able to meet. Thus, it appears that the GDR is being used solely as a facade for the company to argue that the preferred pharmacy fee is not readily calculable at the point of sale and thus need not be reported on the PDE, but rather is a DIR that gets reported after the end of the plan year. If this were true, it would elevate form over the substance of the transactions.

66. In a further attempt to offset at least the large pharmacies' cost in paying Defendant EnvisionRx Options' increased "preferred pharmacy" fee in 2016, the company raised by approximately $1 the dispensing fee it pays to the large pharmacies per prescription. Nevertheless, at least two large pharmacies (Walmart and Sam's Club) no longer participate in the Envision plan.

67. Defendant EnvisionRx Options' Plan Finder contains false and misleading information regarding the pharmacies. For example, the company has had many complaints from members because a pharmacy showed as "preferred" or contracted when they were not. Company management is aware of the defects in Plan Finder, but has not remedied the problems. Moreover, the company's Plan Finder was recently rejected by CMS because such a high percentage of the pharmacies are "preferred." However, CMS is unaware of the reason for this high percentage, namely the pay-to-play model instituted by Defendant EnvisionRx Options beginning in January 2015.

C. Drug Prices, Including Maximum Allowable Cost (MAC), Are Inflated

68. Maximum Allowable Cost ("MAC") is one of the methodologies used by Defendant EnvisionRx Options (and other PBMs) to reimburse pharmacies for prescription drugs under Part D. The PBMs are responsible for calculating/setting the MAC for each drug for each pharmacy it has contracted with. The MAC is adjusted continually (i.e., every seven days)

throughout the year. Contracts between the PBM Defendant EnvisionRx Options and the pharmacies specify whether MAC is the methodology used as the negotiated price. Relators estimate that between 80%-100% of generic drugs have MAC prices available. Defendant EnvisionRx Options typically uses MAC as the negotiated price in its contracts with the pharmacies, and it is the methodology used for all the "preferred pharmacies" described above, at least on generic drugs. If a MAC is not available, Average Wholesale Price ("AWP") or Usual and Customary ("U&C") can be used for a generic drug. In addition, for brand name drugs, AWP or U&C would typically be used, instead of MAC.

69. At the same time Defendant EnvisionRx Options began charging a preferred pharmacy fee (in January 2015), it also began inflating MACs for claims submitted by the major pharmacies (i.e., Rite Aid, CVS, Walgreens), that joined the preferred network and were being assessed the then approximately $5.00-$5.50 fee per Defendant EIC member prescription. The inflated MACs were *only* applied to the Defendant EIC PDP member prescriptions (i.e. not to other PDPs for whom Defendant EnvisionRx Options acted as PBM) and were *only* applied to the major preferred pharmacies. MACs are not inflated for the smaller (i.e. "Mom and Pop") pharmacies, even if they are preferred pharmacies and assessed the preferred pharmacy fee. Indeed, correspondence from these small pharmacies details their concern regarding the insufficient amount of payment on the claim after the preferred pharmacy fee is deducted; indeed, in some cases it was a negative amount.

70. One likely explanation for inflating the MACs beginning in January 2015 for these major pharmacies is that it was a *quid pro quo* for the new preferred pharmacy fee being imposed by Envision. Major pharmacies that joined the Defendant EnvisionRx Options preferred network would receive inflated MACs for EIC claims - higher than MACs for claims submitted

by other PDPs who had Defendant Envision Rx as a PBM– *for the same prescription drug*. Indeed, MACs for Defendant EIC claims were inflated as much as 45%, have increased over time, and cost the Medicare Program millions of dollars for these false and fraudulent claims.

71. Approximately 80% of Defendant Envision Insurance/EIC's about 1.5 million monthly claims are for generic drugs and of those an estimated 60%-80% receive inflated MAC reimbursements. These claims are being inflated anywhere from $3.00 - $15.00 per claim processed through the major pharmacy chains (e.g., CVS, Rite Aid, and Walgreens). *Each month* this inflation is overcharging CMS some $2.5 million - $12.6 million. Thus, for 2015, the approximate total overcharge is $30 million - $151.2 million on some 18 million claims; and the misconduct is continuing in 2016. In addition, there are instances where the preferred pharmacies are receiving a better (i.e. inflated) AWP from EnvisionRx Options for a brand name drug for a Defendant Envision Insurance/ EIC member than for an EIC commercial PDP.

72. These inflated prices render claims for Defendant EIC beneficiaries false or fraudulent and actionable under the FCA. Not only is the MAC improperly inflated (which in and of itself is a violation), but it is inflated ONLY for Defendant EIC PDP beneficiaries, causing CMS to reimburse Defendant EIC (and ultimately the Defendant EnvisionRx Options' "preferred pharmacy") significantly more for the same prescription drug than it would for a beneficiary of another PDP. As Defendant EnvisionRx Options created these prices (i.e. MACs), it as the PBM is knowingly caused the filing of the false or fraudulent claims. As the inflated MACs for each Defendant EIC prescription claim cost Medicare significantly more money, knowledge of the inflation is material to CMS' reimbursement of claims, its reconciliation process, *and* its bid awards.

73. Moreover, the inflated MAC would appear to be a form of kickback offered to the pharmacies in return for their signing up as a "preferred pharmacy" and paying the preferred pharmacy fee(s) described above. Defendant EnvisionRx Options is both offering remuneration (i.e. an inflated MAC) and receiving remuneration (preferred pharmacy fee) in violation of the AKS. The spread the major pharmacies realize by virtue of the inflated MACs more than offsets the preferred pharmacy fees owed to Defendant EnvisionRx Options—so it becomes a "win win" for everyone but the government. At least one purpose of this whole arrangement is for Defendant EnvisionRx Options to "refer" Defendant EIC's PDP members to the "preferred pharmacy."

74. Claims presented to Medicare Part D/CMS for reimbursement resulting from the offer or payment of, or solicitation or receipt of, prohibited remuneration in violation of federal Anti-Kickback Statute are "false" and/or "fraudulent" claims within the meaning of the federal False Claims Act.

75. Moreover, because more than 90% of Defendant Envision Insurance/EIC Medicare Part D plan members are low income subsidy ("LIC" or "LIS"), Defendants are better able to hide from CMS the fact and effect of the increased MACs. This is because LIS beneficiaries' co-pays are a small fixed amount determined by ability to pay, i.e. $1, $3, $5, unlike other members whose co-pay is a percentage of the cost of the prescription and thus would increase, for example, as the MAC and negotiated price increased. At some point, a large number of increased co-pays from one PPS may raise concern with CMS, but in this case, CMS would not see increased co-pays for the some 90% of Defendant EIC's members who are LIS.

76. All Defendants have "knowledge" of this fraudulent scheme within the meaning of the FCA.

D. E-Prescribing Costs Are Misrepresented and not Refunded

77. For the past three plan years (2012-2014), Defendant EIC has placed a bid with CMS to be a PPS and offer a PDP that falsely represents that the e-prescribing service will cost approximately $1.5 million/year. In fact, Defendant EIC has been overcharging CMS for these administrative costs it has incurred from the vendor Surescripts and has not refunded the overpayments. Moreover, on information and belief, the company's bid for the 2015 and 2016 plan years also misrepresent the true cost of e-prescribing services.

78. On behalf of Defendant EIC, Defendant EnvisionRx Options is the conduit to Surescripts. The contract between Defendant EIC (as PPS) and Defendant EnvisionRx Options (as PBM) states that the PBM will pass its costs through to the PPS. However, Defendant EnvisionRx Options has been inflating the per unit charge, falsifying the number of electronic transactions, and overbilling Defendant EIC.

79. In particular, Defendant EnvisionRx Options has charged Defendant EIC approximately $1.1 million annually, and received reimbursement in that amount from Defendant EIC, but has only incurred approximately $700,000 in charges annually. Moreover, each year, after Defendant EIC reports the inflated charges to CMS, and receives payment from CMS, Defendant EnvisionRx Options refunds approximately $1 million to Defendant EIC (i.e. this is in part an accounting trick to benefit the books of Defendant EIC, as Defendant EnvisionRx Options is refunding even more than what it supposedly overcharged Defendant EIC). In other words, the true cost to Defendant EIC ends up being less than $100,000, not the some $1.5 million contained in its bid to CMS. The "logic" used by Defendant EnvisionRx Options to create this recalculation is used only for its client Defendant EIC, *not for any of its other plan sponsor/PDP clients*.

80. Defendant EIC has not refunded or reported any of the approximately $1.4 million overcharge to CMS for any of the plan years in question.

81. Defendants are liable under the FCA for providing CMS with false or fraudulent information regarding the actual cost of the Surescipts' e-prescribing services. This misrepresentation is material as it influences CMS' bid calculations and awards, as well as payments to Defendants. Moreover, the overpayments have not been returned or refunded or reported to CMS.

82. As noted above, Defendant EIC has been a plan sponsor for approximately 8 years, and should be familiar with all the laws and regulations governing its role as a PPS, as well as the Prescription Drug Manual, *supra*, which identifies this conduct as fraud (e.g., improper bid submissions, false information furnished to CMS). Moreover, in 2014, Defendant EnvisionRx Options (as PBM) did an internal audit which confirmed this information. Defendant EIC has "knowledge" of this fraud as that term is used in the FCA; indeed, on information and belief, Defendant EIC has actual knowledge of this information.

E. Double Billing For Drugs Including Under Medicare Parts A, B and D

83. This fraudulent scheme involves Defendant EnvisionRx Options creating false claims to submit to the government for patients/members under Defendant EIC's PDP. There are multiple ways which EnvisionRx Options as the PBM is creating duplicate claims using information captured from claims for Defendant EIC, as well as non-EIC, plan members, and submitting to government health insurance programs through Defendant EnvisionRx Options.

84. For example, some of this double billing involves members who use Cash Cards to get their prescriptions filled at pharmacies; some involves hospice patients who have prescription drug coverage under both Parts B and D (the submission of duplicate claims to Parts

B and D is not easily detected, and has been identified by CMS as an area of significant fraud) and some double billing involves long term care, skilled nursing, and hospital facility members/ patients who have coverage under Parts A and D.

85. The various double billing schemes were enabled at least in part by Defendant TPG's ownership of long term care, skilled nursing, and hospital facilities, as well as their continued high level involvement in the management of Defendant EnvisionRx Options. For example, Defendant TPG has ownership interests in: Assisted Living Concepts (now Enlivant), a long term care provider acquired by TPG in 2013 (the same year TPG acquired Envision) that provides services to more than 9,000 residents in over 200 assisted living communities across the country; and IASIS Healthcare, which owns some owns 15 acute care hospitals, one behavioral hospital and several other facilities, including 132 physician clinics, as well as multiple outpatient surgical units, imaging centers and investments in urgent care centers serving 1.1 million patients. Claims information from these affiliated facilities is captured and used to resubmit through Defendant EnvisionRx Options, creating a duplicate claim. The double billing increases the value of Defendant EnvisionRx Options, as well as the value of the Defendant TPG affiliated facilities at the expense of government health insurance programs.

F. Processing Claims For Sanctioned and/or Unapproved Prescribers

86. There are providers such as physicians who have been sanctioned by the federal and/or state government and thus are not approved to participate in Medicare Part D. In addition, there are health care providers who have no (or limited) prescribing authority under federal or state law, for example, a nurse's assistant. A PBM such as Defendant EnvisionRx Options is supposed to put point-of-sale ("POS") logic in its adjudication system to manage prescriber validation. Instead, Defendant EnvisionRx Options intentionally removed all internal computer

programming which would block claims from prescribers who do not have CMS (or other) approved prescribing authority. In addition, Defendant EnvisionRx Options has intentionally refused to implement adequate programming to prohibit state sanctioned prescribers from access to process claims. It has done all this despite an audit done by Acumen on behalf of CMS in 2014 (for plan year 2013), which found some $12 million in claims for sanctioned providers by EnvisionRx Options for EIC in that one year alone. Company management is aware of the issue and is actively refusing to put in place the necessary safeguards.

G. Harm to the United States: Damages and Penalties

87. The direct financial loss and harm caused to government health care programs, in particular Medicare Part D, by the improper and illegal conduct described above is substantial. In addition, there are indirect and intangible harms to the government.

88. For example, Relators estimate that the fraudulent reporting of negotiated price/preferred pharmacy fee on the PDEs, has caused direct damages totalling about $31.2 million for the 2015 plan year on some 18 million claims and the conduct is continuing. Moreover, the misconduct affects bid submissions and CMS payment calculations. There are also indirect harms and losses caused by Defendants' fraudulent conduct with respect to failing to report an accurate negotiated price. CMS has recognized that inaccurate reporting on costs of administering the Part D program harms the very integrity of the program. In its September 29, 2014 Memorandum to all Part D sponsors (this would include Defendant EIC), CMS "expressed its concerns regarding the differences with which Part D sponsors report costs and price concessions to CMS …[and that] variations in the treatment of costs and price concessions affect beneficiary cost sharing, CMS payments to plans, federal reinsurance and low income cost-sharing (LICS) subsidies, manufacturer coverage gap discount payments, and plan bids" and can

undermine a level playing field in bidding and cost reporting. *See* 79 FR 29843, 29878 (May 23, 2014) quoted in CMS Letter dated September 29, 2014 to "All Part D Sponsors and interested parties" regarding "Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions.

89. By way of further example, Defendants' fraudulent inflation of the MAC pricing on the PDEs resulted in an estimated total overcharge to Medicare Part D of some $30 million to $151.2 million on some 18 million claims in 2015, with the misconduct continuing in 2016. Moreover, to the extent the inflated MAC was part of a kickback arrangement in violation of the AKS and the FCA, all the intangible harms Congress sought to avoid through passage of the Anti-Kickback Statute come into play. These include, for example: goods and services being provided that are medically inappropriate, unduly costly, medically unnecessary, of poor quality, or even harmful to a vulnerable patient population, and the playing field among health care providers not being kept level.

VI. CLAIMS FOR RELIEF

Count I

Federal False Claims Act
31 U.S.C. § 3729(a)(1)(A) (2009)

1. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

2. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq*. as amended.

3. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval.

4. The Government, unaware of the falsity of all such claims made or caused to be made by Defendants, has paid and continues to pay such false or fraudulent claims that would not be paid but for Defendants' illegal conduct.

5. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

6. Additionally, the United States is entitled to the maximum penalty of up to $11,000 or the statutory maximum for each and every violation alleged herein.

Count II

Federal False Claims Act
31 U.S.C. § 3729(a)(1)(B) (2009)

7. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

8. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq*. as amended.

9. By and through the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

10. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

11. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

12. Additionally, the United States is entitled to the maximum penalty of up to $11,000 or the statutory maximum for each and every violation alleged herein.

Count III

Federal False Claims Act
31 U.S.C. § 3729(a)(1)(G) (2009)

13. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

14. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* as amended.

15. By and through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay money to the Government and they have concealed and improperly avoided an obligation to pay money to the Government, including specifically Defendants' obligation to report and repay past overpayments of Medicare claims for which Defendants knew they were not entitled to and therefore refunds were properly due and owing to the United States.

16. The Government, unaware of the concealment by the Defendants, has not made demand for or collected the years of overpayments due from the Defendants.

17. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

18. Additionally, the United States is entitled to the maximum penalty of up to $11,000 or the statutory maximum for each and every violation alleged herein.

Count IV

Federal False Claims Act
31 U.S.C. § 3729(a)(1)(C) (2009)

19. Relators reallege and incorporate by reference the allegations contained in the foregoing paragraphs above as though fully set forth herein.

20. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq*. as amended.

110. By and through the acts described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A), (B), and (G). Further to Defendants' conspiracy and fraudulent scheme, despite knowing that tens of millions of dollars in payments from the federal government have been received in violation of the False Claims Act and in violation of the Anti-Kickback Statute's prohibition on receipt of payment for services rendered in connection with an improper financial arrangement, Defendants have refused and failed to refund these payments and have continued to submit false or fraudulent claims, statements, and records to the United States.

111. The Government, unaware of the Defendants' conspiracy and fraudulent schemes, has paid and continues to pay claims that would not be paid but for Defendants' illegal conduct.

112. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

113. Additionally, the United States is entitled to the maximum penalty of up to $11,000 or the statutory maximum for each and every violation alleged herein.

VII. PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs-Relators pray for judgment against Defendants as follows:

a. that Defendants cease and desist from violating the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq*;

b. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 (or other statutory maximum provided for by law) for each violation of 31 U.S.C. § 3729;

c. that Plaintiffs-Relators be awarded the maximum amount allowed pursuant to the False Claims Act, 31 U.S.C. § 3730(d);

d. that Plaintiffs-Relators be awarded all attorneys' fees, costs, and expenses pursuant to the False Claims Act, 31 U.S.C. § 3730(d); and

e. that the Plaintiffs United States and Relators recover such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs-Relators hereby demand a trial by jury.

Dated: January 22, 2016

Respectfully Submitted,

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